

### REMARKS

Claims 56-60 and 62-106 are currently pending in the application. Claims 56-60 and 62-87 stand rejected as claims 88-106 are withdrawn. Applicants amend claims 56, 76 and 88, inter alia, by adding the word "repeatedly" before the word "penetrating" in the preamble with support found on page 6, lines 21-34.

Claims 56-58, 60, 62-64, 76, and 78-83 are rejected under 35 U.S.C. 103(a) as being unpatentable over Henderson (U.S. Patent No. 3,064,651) in view of Hickey (U.S. Patent No. 2,697,438). Claims 70, 71, 74, 75, 85 and 87 are rejected under 35 U.S.C. 103(a) as being unpatentable over Henderson, Bitner (U.S. Patent No. 5,515,872) and Hickey as applied to claims 56, 65, 69 or 84 and further in view of Kaneko (U.S. Patent No. 6,517,523).

Regarding independent claims 56 and 76, the office action maintains that a hypothetical person of ordinary skill in the art would combine the teachings of Henderson and Hickey and thereby provide the needle disclosed by Henderson with a point that is arranged to lie substantially on a longitudinal centre line of the needle as disclosed by Hickey. Applicants respectfully traverse as set forth below.

Hickey discloses:

The...design provides a penetrating point which is at the axis of the cannula. The location of the penetrating point below the imaginary extension of the outer cylindrical surface of the cannula and the concave curvature of the surface 8, 10, 10 facilitate the unrestricted flow of fluid through the opening 7 because, due to the curvature of the surface 8, 10, 10 the surrounding tissue will not be tightly pressed against all portions thereof, particularly the middle portion of said surface. (col. 2, lines 6-16)

Thus, the supposed advantage of positioning the point of the needle disclosed by Hickey along the longitudinal centre line of the needle is to facilitate the flow of fluid through the

opening in combination with the curvature of the surfaces of the needle opening when the needle is pushed into and encased in solid skin tissue.

In contrast, the needle according to the claimed invention is arranged to pass through a membrane, such as a vial membrane to be located at a position beyond the membrane in a gas filled or liquid filled space. When designing a needle for repeatedly penetrating a membrane of a vial for example, the flow of liquid through the opening of the needle will not be restricted by solid matter when the needle is used to inject or withdraw liquid from the vial. A skilled person would therefore have no reason to provide a needle for repeatedly penetrating a vial membrane with a point located along the longitudinal centre line of the needle, since the problem solved by such a feature in Hickey's disclosure does not occur when merely penetrating the membrane of a vial.

Furthermore, one of ordinary skill would not seek to provide the needle disclosed by Henderson with a point that lies along the longitudinal centre line of the needle as this would entail an additional manufacturing step. In particular, once a needle point has been prepared by providing the end of a cylinder with a beveled edge as taught in figure 3 of Henderson) the needle point would then be bent towards the longitudinal centre line of the needle. A skilled person would not seek to perform this additional manufacturing step without good reason nor to solve a problem that does not exist when using the needle disclosed by Henderson.

Accordingly, neither Hickey, Henderson, nor the combination thereof discloses at least a "needle for repeatedly penetrating a membrane [wherein the] outer edges present on the pointed end in the area from the point to a position beyond the opening are rounded so that after the initial penetration the pointed end will push the membrane material away rather than cutting the membrane material; and wherein the point is arranged to lie substantially on a longitudinal centre line of the needle when viewed along the longitudinal centre line of the needle," as recited in independent claim 56 or wherein "the point of the penetrating tip is arranged to lie substantially on the longitudinal centre line of the needle when viewed along the longitudinal centre line of the needle, and the penetrating tip is designed with a cross section having a symmetry causing at least three substantially equally sized forces (F) in different directions which are radial to the longitudinal centre line of the needle and which forces counteract each other so that the needle

will tend not to deviate from the initial penetration direction when the needle penetrates a membrane," as recited in independent claim 76.

Accordingly, Applicants submit that claims 56 and 76 are patentable over the combined references and that the dependent claims are likewise allowable for at least the same reasons discussed above. Thus, Applicants respectfully request withdrawal of the rejections under Section 103 and reconsideration of the claims.

### CONCLUSION

It is believed that all of the pending claims have been addressed. However, the absence of a reply to a specific rejection, issue or comment does not signify agreement with or concession of that rejection, issue or comment. In addition, because the arguments made above may not be exhaustive, there may be reason for patentability of any or all pending claims (or other claims) that have not been expressed. Finally, nothing in this paper should be construed as an intent to concede any issue with regard to any claim, except as specifically stated in this paper, and the amendment of any claim does not necessarily signify concession of unpatentability of the claim prior to amendment. Applicants respectfully request consideration of all filed IDS' not previously considered, by initialing and returning each Form 1449.

All fees are being paid concurrently herewith on the Electronic Filing System (EFS) by way of Deposit Account authorization. Please apply all charges or credits to Deposit Account No. 06-1050.

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Page : 12 of 12

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Respectfully submitted,

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